

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA**

MAUREEN PIEKANSKI

Plaintiff,

v.

ALEX M. AZAR II, in his official
capacity as Secretary of the United
States Department of Health and
Human Services,

Defendant.

No. 3:20-CV-00687

(Hon. Martin Carlson)

(Electronically Filed)

**DEFENDANT'S REPLY IN SUPPORT OF HIS
MOTION TO DISMISS**

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I. INTRODUCTION

Plaintiff fails to establish Article III standing, because she has suffered no injury-in-fact that could be redressed by a favorable ruling. It remains undisputed that, no matter the outcome, Plaintiff has no financial responsibility related to the claim on appeal. Absent any concrete injury, Plaintiff asserts that she has a substantive “right” to require Medicare, rather than Novocure, to bear the cost of her claims. However, the Third Circuit held that a plaintiff lacks standing to shift the costs of medical claims from one party to another because she “never has had anything to gain from this lawsuit.” *Wheeler v. Travelers Ins. Co.*, 22 F.3d 534, 538 (3d Cir. 1994). In addition, Plaintiff’s assertion that she may become personally liable at some point in the future is pure speculation, made even more unlikely by the fact that Medicare has covered her recent claims under the 2019 LCD. In *Pehoviack v. Azar*, the district court recently dismissed an identical TTFT claim appeal, finding that a plaintiff who was not required to pay for her treatment and alleged possible future injuries lacked standing. 20-CV-661, Dkt. 22 at *5 (C.D. Cal. July 22, 2020).

Because Plaintiff’s alleged injury is a “bare procedural violation, divorced from any concrete harm” that does not satisfy the standing requirements of Article III, her complaint should be dismissed. *Spokeo, Inc. v. Robins*, 136 S.Ct. 1540, 1549 (2016).

II. ARGUMENT

Plaintiff has failed to allege facts showing she (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision. *Spokeo*, 136 S.Ct. at 1547 (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)).

A. Plaintiff Has Not Suffered an Injury in Fact.

1. Plaintiff has not alleged an injury-in-fact.

It is undisputed that Plaintiff has not suffered any tangible injury, because the ALJ found she has no financial responsibility for the claim on appeal. AR at 3154. Although Plaintiff alleges that her claim appeal was wrongly decided, “Article III standing requires a concrete injury even in the context of a statutory violation.” *Spokeo*, 136 S.Ct. at 1549; *see also Kamal v. J. Crew Group*, 918 F.3d 102, 113 (3d Cir. 2019) (“If the violation does not present a ‘material risk of harm to that underlying interest,’ however, a plaintiff fails to demonstrate concrete injury.”) (citing *Spokeo*, 136 S. Ct. at 1549).¹

The Supreme Court’s decision in *Thole* is dispositive as to Plaintiff’s lack of standing. *Thole v. U.S. Bank N.A.*, 140 S.Ct. 1615 (2020). In *Thole*, the Court held

¹ Although Plaintiff overlooks recent precedent in favor of older Supreme Court decisions (Pl. Opp. at 3), her cited cases still required that a plaintiff alleging a statutory violation must have also suffered a concrete injury in order to have Article III standing. *See Warth v. Seldin*, 422 U.S. 490, 501 (1975); *Linda R.S. v. Richard D.*, 410 U.S. 614, 617 (1973).

that a plaintiff lacks Article III standing where the outcome of a lawsuit will not affect the amount of a benefit payment. *Id.* at 1619. Likewise, the district court in *Pehoviack* recently held:

This action must be dismissed because Plaintiff lacks Article III standing. As provided in the MAC Decision, the supplier of Plaintiff's TTFT device—not Plaintiff herself—was found “financially liable” and “responsible.” Plaintiff was not required to pay for her treatment. Nor does Plaintiff allege that she has been otherwise injured by the MAC Decision.”) (citation omitted).

Id. at *5. Here, Plaintiff has no concrete injury, because she has no financial responsibility for her claim, and thus no Article III standing despite any alleged statutory violation.

Absent any concrete injury, Plaintiff asserts that she has a “substantive” right for Medicare, rather than Novocure, to bear the expense of her claim. Plaintiff's Opposition [Dkt. No. 40] (“Pl. Opp.”) at 3-5. However, two elements must be present for a statutory violation to constitute a cognizable injury:

(1) Congress must have determined that the statutory violation is a sufficient injury to satisfy Article III; and (2) the harm must have “long been seen as injurious” under the common law. *See Spokeo*, 136 S.Ct. at 1549; *Kamal*, 918 F.3d at 111-15. Neither element is present here.

First, there is no “congressionally created entitlement to Medicare coverage,” (Pl. Opp. at 3), much less any law stating that a beneficiary has been injured absent any financial responsibility for her claim. To the contrary, coverage

for durable medical equipment, such as the Optune device, cannot be made *unless* the device is “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” 42

U.S.C. § 1395y(a)(1)(A). CMS has broad authority to determine whether Medicare covers particular medical services, and beneficiaries must submit claims in order to obtain coverage. Defendant’s Memorandum of Law [Dkt. No. 35] (“D. Mem.”) at 3-5. If a claim is denied, the beneficiary must exhaust administrative remedies before proceeding to federal court. *Id.* at 5-6. The Secretary has discretion to approve or reject claims, and the law merely affords beneficiaries the *procedural right* to challenge a claim denial. No statute guaranteed that Plaintiff’s claim would be covered, and no statute identifies what injury a beneficiary paying nothing out-of-pocket has suffered. Here, Plaintiff merely alleges that her claim appeal was wrongfully decided, which is a procedural violation “divorced from any concrete harm” that cannot “satisfy the injury-in-fact requirement of Article III.” *Spokeo* at 1549; *see also Thole*, 140 S.Ct. at 1619-20; *see, e.g., California Clinical Laboratory Ass’n v. Secretary of HHS*, 104 F. Supp. 3d 66, 76-78 (D.D.C. 2015) (finding that the right to file an LCD challenge was not sufficient for standing, because it was procedural and merely a “means to achieve the ultimate

end the recipients seek.’’).²

Second, the Third Circuit has rejected the proposition that Plaintiff has standing to sue Medicare despite her claim being fully paid by Novocure. In *Wheeler*, the plaintiff incurred medical expenses in connection with an automobile accident, all of which were fully paid between Medicare and Travelers. 22 F.3d at 536. Nevertheless, plaintiff sued Travelers for the portion of expenses paid by Medicare. *Id.* The Third Circuit held that plaintiff did not have Article III standing, because “[s]he has not alleged or established that she suffered any actual or threatened injury from Travelers’ denial of her claim for no-fault benefits for she acknowledges that Medicare paid the medical expenses for which she seeks a recovery.” *Id.* at 538. Plaintiff’s allegation that “Travelers wronged, but did not injure her” was insufficient for standing. *Id.*; see, e.g., *Hull v. Burwell*, 66 F. Supp. 3d 278, 282 (D. Conn. 2014) (citing *Wheeler* and finding that a plaintiff had no standing to sue Medicare where the Medicaid program had assumed all of plaintiff’s liability); *Estate of Lake v. Secretary of HHS*, 1989 WL 200974, at *2 (D.N.H. Oct. 27, 1989) (finding that a plaintiff lacked standing to sue for Medicare reimbursements where she had no out-of-pocket loss).

² The case of *Bock v. Pressler & Pressler, LLP* is inapposite, because the Fair Debt Collection Practices Act was Congressionally-designed to give consumers the right to truthful information and the plaintiff alleged monetary damages. 254 F. Supp. 3d 724, 735 (D.N.J. 2017); see also D. Mem. at 12 (distinguishing procedural from substantive rights under *Spokeo*).

Citing *Wheeler* as controlling law, the Third Circuit held that a party who “no longer has anything personally to gain from a favorable outcome” because it has been fully indemnified and signed over its right to any recovery, had no standing. *Koons v. XL Ins. Am., Inc.*, 620 F. App’x 110, 112-13 (3d Cir. 2015). Likewise, Plaintiff has no out-of-pocket liability and nothing to gain from arguing that Medicare, rather than Novocure, should be financially responsible for paying her claim.

Meanwhile, Plaintiff’s cited cases are inapposite. *See* Pl. Opp. at 3. The Supreme Court’s decision in *Heckler v. Ringer* did not analyze Article III standing, but rather discussed claims “arising under” the Medicare Act and the limitations on federal jurisdiction except under 42 U.S.C. § 405(g). 466 U.S. 602, 620 (1984). A respondent alleged that the Secretary’s refusal to allow payment precluded him from having an operation. Plaintiff’s quotation is taken out of context:

As to § 1331 jurisdiction, as with the other three respondents, all aspects of [respondent’s] claim “aris[e] under” the Medicare Act in that the Medicare Act provides both the substance and the standing for [respondent’s] claim, *Weinberger v. Salfi*, 422 U.S., at 760–761, 95 S.Ct., at 2464–2465. Thus, consistent with our decision with respect to the other three respondents, we hold that §§ 1331 and 1361 are not available as jurisdictional bases for vindicating [respondent’s] claim.

Id. at 620-21. The Court did not conclude that any statutory violation of the Medicare Act is substantive in nature; rather the Court found that respondent’s claim for payment arose under the Medicare Act (and not under other jurisdictional bases).

The respondent's claim is also distinguishable, because he alleged a tangible economic injury, which Plaintiff has not suffered.

Plaintiff also cites several district court decisions finding standing where Medicaid paid claims that were denied by Medicare. Pl. Opp. at 4-5. However, the *Martinez* (1986) and *Longobardi* (1988) decisions are “inconsistent with modern standing precedent of the Supreme Court because they rely on a notion that standing may be founded on no more than an abstract ‘entitlement’ right created by statute without focus on whether a plaintiff has sustained a practical, concrete injury from the claimed violation of the statutory right.” *Hull*, 66 F. Supp. 3d at 284. The *Anderson* (2010) decision relied on *Longobardi*, and the *Ryan* (2015) decision relied upon *Martinez*, *Longobardi*, and *Anderson*. These decisions, which are inconsistent with and pre-date the Supreme Court and Third Circuit precedent discussed above, are not persuasive.

2. Plaintiff has not alleged an “impending” future injury that could give rise to standing.

Alleging no concrete injury, Plaintiff asserts that the ALJ decision denying coverage may cause her future injury. Pl. Opp. at 5-8. In particular, Plaintiff asserts that if her claim denial is not reversed, she might be held personally liable for future claims under either 42 U.S.C. § 1395pp or an ABN issued by Novocure. *Id.* Plaintiff, however, overlooks that speculative, hypothetical, or possible future harms cannot establish standing, and that an injury must be “impending to

constitute injury in fact.” *Lujan*, 504 U.S. at 564 & n.2; *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 409 (2013). The mere possibility that Plaintiff’s claim *might* be denied in the future, and that Plaintiff *might* be financially responsible for that claim, cannot create standing. Indeed, Plaintiff alleges that her other TTFT claims have been approved, and offers no reason why they might be denied in the future. See FAC ¶¶ 20-30; see, e.g., *Pehoviack* at *5 (“Plaintiff argues . . . that she may be held personally liable for future treatments, or that her TTFT supplier might require her to sign an agreement assuming liability for the costs of future Medicare denials. None of these potential injuries, however, has come to pass; indeed, Plaintiff has received favorable Medicare decisions for treatment periods subsequent to the denial at issue here.”) (citation omitted); *Cal. Clinical*, 104 F. Supp. 3d at 80 (finding that a “speculative chain of possibilities” regarding the potential for future claim denials was not an “impending” injury) (quoting *Clapper*, 568 U.S. at 414).

Even assuming that a claim denial were impending, which it is not, section 1395pp does not afford Plaintiff standing. Section 1395pp(b) states that “in the case of *comparable situations* arising thereafter with respect to such individual, [she] shall, by reason of such notice . . . be deemed to have knowledge that payment cannot be made for such items or services.” (emphasis added). Plaintiff does not dispute, however, that there was a significant change between the 2014

LCD, which categorically denied coverage for TTFT, and the 2019 LCD, under which her recent TTFT claims have been approved. D. Mem. at 4-5, 14. It is highly unlikely that an ALJ would deem Plaintiff to have knowledge that her TTFT claim would be denied under the 2019 LCD, given a denial in different circumstances under the 2014 LCD. It is even more far-fetched to believe that the Secretary would hold Plaintiff personally liable given that the decision on appeal explicitly found no “evidence demonstrating the Beneficiary knew or should have known that the device at issue would not be covered by Medicare.” AR at 3154.³ And, even in the unlikely event that Plaintiff were held personally liable, she could still appeal to federal court. Standing cannot be based upon the hypothetical, and distinctly unlikely, possibility that the instant claim denial could influence the decision of a judge to find Plaintiff personally liable at some unknown point in the future. *See, e.g., Hull*, 66 F. Supp. 3d at 282-83 (finding that plaintiff’s potential liability under section 1395pp(b) was “wholly contingent upon the future acts or omissions of third parties” and failed to establish an impending injury).

³ Plaintiff’s “Exhibit A” should be stricken or disregarded, because it is outside the administrative record and the First Amended Complaint. *See* 42 U.S.C. § 405(g) (requiring review “upon the pleadings and transcript of the record”); *Matthews v. Apfel*, 239 F.3d 589, 593-94 (3d Cir. 2001) (excluding evidence that was not before an ALJ at the time of his decision); *see also Baker v. Barnhart*, 457 F.3d 882, 891 (8th Cir. 2006) (holding that the district court abused its discretion by taking judicial notice of evidence outside the administrative record). In addition, an ALJ decision regarding another beneficiary is irrelevant.

Second, the Secretary anticipated that Plaintiff may argue that the outcome of this lawsuit could affect Novocure's choice to have Plaintiff sign an ABN at some point in the future. D. Mem. at 14-15. Plaintiff offers no response and fails to plead facts showing that Novocure has ever billed Plaintiff or would bill Plaintiff in the future, much less that an ABN from Novocure is "impending." *Id.* Plaintiff's chain of speculation regarding the possible actions of a third party does not create standing.

B. Plaintiff Cannot Satisfy the Second and Third Elements of Standing Either.

Plaintiff makes little attempt to show that the second and third elements of standing are present. Pl. Opp. at 7-8. Plaintiff does not dispute that Novocure has complete discretion as to whether to bill Plaintiff for her treatment, and that any independent action that Novocure takes is not traceable to the Secretary. *See* Br. at 15-16. Plaintiff also fails to meet the third element of standing, because, no matter the outcome of this lawsuit, Novocure has the discretion to require Plaintiff to sign an ABN. *Id.*

CONCLUSION

For the foregoing reasons, and because Plaintiff's lack of standing cannot be rectified by amending her Complaint, the Secretary respectfully requests that the Court dismiss the First Amended Complaint with prejudice.

Respectfully submitted,

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Dated: August 6, 2020

CERTIFICATE OF SERVICE

I hereby certify that on this date, a true and correct copy of the foregoing
Reply in Support of Defendant's Motion to Dismiss was filed and served upon all
counsel of record through the Court's CM/ECF system.

/s/ Eric S. Wolfish
ERIC S. WOLFISH
Special Assistant United States Attorney

Dated: August 6, 2020